Australian Government

PCT/AU2004/000707

REC'D 22 JUN 2004
WIPO PCT

**PRIORITY DOCUMENT**
SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

**Patent Office**
**Canberra**

I, LEANNE MYNOTT, MANAGER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003904676 for a patent by NEPHI PTY LTD as filed on 29 August 2003.

WITNESS my hand this
Tenth day of June 2004

LEANNE MYNOTT
MANAGER EXAMINATION SUPPORT AND SALES

BEST AVAILABLE COPY

P/00/009
Regulation 3.2

AUSTRALIA

*Patents Act 1990*

# PROVISIONAL SPECIFICATION

Invention Title: "SYSTEM, METHOD AND APPARATUS"

The invention is described in the following statement:

# TITLE

SYSTEM, METHOD AND APPARATUS

## FIELD OF THE INVENTION

The invention relates to a system, method and apparatus for treating medical conditions. In particular, although not exclusively, the invention relates to articles comprising non-invasive means for stimulating a plurality of acupoints in various regions of a body of a wearer of the article to treat conditions such as, but not limited to, incontinence and enuresis in the wearer.

## BACKGROUND TO THE INVENTION

Acupuncture and acupressure are known methods of treatment of acute and chronic pain. These methods are also used for the treatment of conditions such as incontinence and a range of other medical conditions in the body. During acupuncture, needles are inserted into the skin and twisted over known and specific body acupuncture points and/or meridian points to trigger electric currents along the nerve or meridian pathways. Sometimes the needles are heated to intensify the treatment. During acupressure, pressure is applied to specific acupoints or meridian points to achieve the same effect.

One drawback of acupuncture is its invasive nature and the experienced or anticipated pain involved deters many people from undergoing acupuncture. Another problem is that both acupuncture and acupressure require the patient to temporarily cease their everyday activities and, for example, lie down and/or remain stationary to enable an acupuncturist/acupressure expert to administer treatment.

The use of magnets to relieve pain and accelerate healing has also long been known. When permanent magnets are placed over known acupuncture/acupressure sites the electrical potential of the points changes, which causes a current to flow of the order of 10μA. The electrical signal is transmitted from the acupoint nerve point to the acupoint nerve/nerves and/or meridian channels including the Central Nervous System (CNS) to achieve a beneficial therapeutic effect on the body. Blood flow in the capillaries is increased, thus speeding up fluid exchange at the pain/injury site. Although magnets are not considered to provide treatment as effective as acupuncture, magnetic treatment has the advantage over acupuncture that it is non-invasive and not painful. The World Health Organisation has also stated that the use of static magnets on the body have no detrimental effect for magnets with a magnetic field strength of up to 20,000 Gauss (2 Tesla).

The incorporation of magnets in a garment for treatment of medical conditions is disclosed in Chinese Patent Application CN 1282548 in the names of Ling Li and Dingxin Ge. CN 1282548 discloses a pair of underpants comprising circular magnets attached to the material of the underpants at the front and back of the underpants at positions corresponding to the acupoints of a wearer. Seven acupoints at the back of the body and four acupoints at the front of the body are covered by magnets. The underpants are for the treatment of senile enuresis, incontinence and other medical conditions.

One problem associated with the underpants of CN 1282548 is that although the magnets are attached to the pants such that they lie adjacent specific acupoints of the wearer, the pants are not of a design that maintains the magnets accurately in position. Movement of the pants during use can cause the magnets

to move away from the acupoints of the wearer, thus reducing the efficacy of the treatment. Another drawback of the underpants of CN 1282548 is that often the magnets attract each other and stick together making the pants difficult to put on. This can nullify the effect of the magnets on the acupoints especially if they stick together when a person is asleep.

The incorporation of magnets into other types of wearable articles used for the alleviation of pain is also known. For example, articles formed from flexible materials comprising one or more magnets are shaped to suit a body region, such as the waist, elbow or wrist and often include strips of Velcro® or other fastening means to secure the article in place. The effectiveness of such articles to alleviate pain relies on the correct positioning of the articles over the relevant area.

Another method for the treatment of conditions such as incontinence are pelvic floor (or Kegel) exercises, which are intended to exercise, strengthen and tone the pelvic floor muscles. However, people often find it difficult to correctly identify the pelvic floor muscles despite tuition, often because of severe muscle deterioration caused by childbirth, menopause or aging, or for other reasons. Consequently, the exercises are performed incorrectly, if at all, and very little benefit is gained.

Hence, there is a need for a method and/or system and/or article for the treatment of medical conditions such as incontinence, menstruation problems, nocturia and other conditions that is/are straightforward for a sufferer to use or follow, preferably without interfering substantially with their daily routine and which provide(s) effective treatment for their condition(s).

## DISCLOSURE OF THE INVENTION

According to one aspect, although it need not be the only or indeed the broadest aspect, the invention resides in an article for the treatment of at least one medical condition, said article comprising:

at least one magnet held by at least one mounting member, said mounting member coupling said at least one magnet to said article;

wherein said at least one magnet lies adjacent a body region comprising at least one acupoint related to said medical condition, said at least one magnet stimulating said at least one acupoint.

Preferably, a plurality of magnets are held by each said mounting member and coupled to said article such that a plurality of acupoints in a plurality of body regions including at least a lumbar region, a sacral region, a perineal region and a lower abdominal region of the wearer are stimulated simultaneously.

Preferably, said magnets are rare earth Neodymium-Iron-Boron (NdFeB) magnets. Alternatively, said magnets may be Ferrite (Fe) magnets.

Preferably, said magnets are between about 10mm and about 25mm in diameter and between about 2mm and about 5 mm in thickness.

Suitably, the magnetic flux density of said magnets may be between about 9,000 and about 13,000 Gauss. Preferably, the magnetic flux density of said magnets is between about 10,000 and about 11,300 Gauss.

Alternatively, said magnets may be about 3mm in diameter with a magnetic flux density of between about 2,000 and 3,000 Gauss.

Preferably, said mounting members are coupled to said article substantially horizontally, substantially perpendicular to the wearer's spine.

Preferably, said magnets adjacent the lumbar region, sacral region and

lower abdominal region have their north pole facing the body.

Preferably, one of said magnets adjacent the perineal region has its north pole facing the body and another of said magnets adjacent the perineal region has its south pole facing the body.

Suitably, said article is formed from a material comprising about 54% polyester, about 30% cotton and about 16% elastane.

Alternatively, said article is formed from a material comprising between about 87% and about 88% cotton and between about 11% and about 12% elastane.

Preferably, said article comprises a locator band formed about an upper region of said article to aid the wearer in correctly positioning said article about the wearer's body and to aid in supporting the mass of the magnets.

Preferably, said locator band is formed about the article below a waistband of the article such that the locator band is located just above the wearer's hipbone. This then locates the waistband correctly when pulled up into position.

Preferably, said locator band is elasticized. According to another aspect, the invention resides in a system for the treatment of at least one medical condition in the pelvic region, said system comprising:

one or more articles worn by a wearer, each said article comprising at least one magnet held by at least one mounting member, said at least one mounting member coupling said at least one magnet to said article such that said at least one magnet lies adjacent a body region comprising at least one acupoint related to said medical condition, said at least one magnet stimulating said at least one acupoint;

a feedback device comprising:

a probe for insertion into an orifice in the pelvic region;

an inflation means coupled to the probe to inflate the probe;

a pressure gauge to measure and display a level of inflation of said inflation means;

wherein said at least one magnet stimulates said at least one acupoint, said stimulation enabling said wearer to activate one or more of their pelvic floor muscles, said feedback device providing feedback to the wearer to confirm correct activation of said one or more pelvic floor muscles after said magnetic stimulation.

According to a further aspect, the invention resides in a method of treating at least one medical condition, said method including the steps of:

stimulating at least one acupoint related to said medical condition using at least one magnet, said at least one magnet mounted on a mounting member coupled to an article worn by a wearer such that said at least one magnet lies adjacent a body region comprising the at least one acupoint;

identifying pelvic floor muscles using a feedback device, said feedback device comprising:

a probe for insertion into an orifice in the pelvic region;

an inflation means coupled to the probe to inflate the probe;

a pressure gauge to measure and display a level of inflation of said inflation means;

and

exercising said pelvic floor muscles according to prescribed pelvic floor exercises, correct activation of said pelvic floor muscles being confirmed by feedback from said feedback device.

The method may include the further step of simultaneously stimulating at

least one acupoint about an ankle and/or lower leg using at least one magnet incorporated in an article worn about the ankle and/or lower leg.

Further aspects and features of the present invention will become apparent from the following detailed description.

## BRIEF DESCRIPTION OF THE DRAWINGS

To assist in understanding the invention and to enable a person skilled in the art to put the invention into practical effect preferred embodiments of the invention will be described by way of example only with reference to the accompanying drawings, wherein:

FIG 1 shows a front side view of one embodiment of the article of the present invention;

FIG 2 shows a rear view of the article shown in FIG 1;

FIG 3 shows a partially cutaway side view of the article shown in FIG 1;

FIG 4 shows an inflation means in the form of a deformable bulb coupled to a pressure gauge in the form of an aneroid sphygmomanometer and a tube;

FIG 5 shows a probe/sensor for insertion into an orifice and for coupling to the tube shown in FIG 4;

FIG 6 shows a flow chart of the method of the present invention;

FIG 7 shows a mounting member for coupling the magnets to the article;

FIG 8 shows a front view of an alternative embodiment of the article of the present invention; and,

FIG 9 shows a rear view of the article shown in FIG 8.

## DETAILED DESCRIPTION OF THE INVENTION

According to one aspect, the present invention comprises one or more articles worn on or about the body, each article comprising at least one, but preferably a plurality of magnets to stimulate at least one and preferably a plurality of acupoints to treat at least one medical condition.

According to another aspect, the present invention is a system for the treatment of at least one medical condition. The system comprises one or more of the aforementioned articles worn adjacent a region of the body that comprises at least one acupoint related to the medical condition being treated. The system may also comprises a feedback device to aid a patient in identifying their pelvic floor muscles and to enable the patient to correctly perform pelvic floor exercises and monitor the condition of their pelvic floor muscles.

A further aspect of the invention is a method of treating medical conditions including the step of wearing for a specified period of time, one or more article comprising magnets on or about the body. For the treatment of certain medical conditions, such as urinary incontinence and enuresis, the method further includes the steps of using the feedback device to correctly identify pelvic floor muscles, performing pelvic floor exercises and monitoring the condition of the pelvic floor muscles.

Whilst it is known that the stimulation of specific acupoints affects particular parts of the body, as detailed in, for example, Acupuncture Charts, China Cultural Corporation, 5th Ed. (1996) ISBN 962 205 002 6, the Applicant has identified that it is not necessary to stimulate specific, individual acupoints. Instead, one or more suitably oriented magnets of suitable magnetic field strength can be employed to

stimulate a plurality of acupoints in a region of the body comprising one or more acupoints related to the medical condition being treated. The relevant region of the body is thus flooded with the magnetic field from the one or more magnets.

With reference to FIGS 1-3, the article according to one aspect of the present invention may be in the form of an undergarment such as a pair of underpants 2 comprising an elasticised waistband 3. However, the article is not limited to such an embodiment and the article may be in the form of, for example, a knee strap, a lower leg sock or other body covering adapted to be worn on or around a specific region of the body.

The article is formed from a material that is soft to the touch and therefore comfortable to wear. The material of the article possesses elastic properties such that it conforms to the contours of the body region upon or about which the article is worn, thus preventing excessive movement of the magnets coupled to the article away from their intended position adjacent the relevant region of the body. The material also needs sufficient structural integrity to accommodate one or more magnets. The Applicant has identified that a material comprising about 54% polyester, about 30% cotton and about 16% elastane (such as Lycra® or Spandex) is particularly effective in fulfilling these requirements. However, the Applicant has also identified a material comprising about 87-88% cotton and about 11-12% elastane is also suitable for fulfilling these requirements. The material is elasticised in two perpendicular directions ("two-way stretch") and only a single layer of the material is required for the article. The need for only a single layer prevents overheating of the body and the constituent materials allow the body to breathe, both of which are important considerations in the treatment of many

medical conditions.

The article comprises at least one and preferably a plurality of magnets located on the article such that the magnet(s) lie adjacent the body generally in the region comprising the acupoints that are relevant to the condition to be treated.

The magnets have a magnetic field sufficiently strong to penetrate the wearer's skin and tissue and stimulate the acupoints to treat a particular condition. The necessary penetration depth varies with the body weight and fat tissue of the wearer and the particular acupoint(s) to be stimulated. It is therefore important to use magnets that are sufficiently strong to penetrate the required depths for all applications. Therefore the magnets need to be sufficiently large to possess a sufficiently strong magnetic field, but cannot be too large otherwise the article will be uncomfortable to wear.

The Applicant has identified that rare earth Neodymium-Iron-Boron (NdFeB) or Ferrite (Fe) magnets available from, for example, Australian Magnet Technology Pty. Ltd. of New South Wales, Australia, are very effective. The magnets are sufficiently small that they are not uncomfortable for the wearer or externally visible or add a significant mass to that of the article. Circular magnets having a diameter of between about 10mm and about 25mm and a thickness of between about 2mm and about 5 mm have been employed in the present invention. The Applicant has found that circular magnets having a diameter of about 10mm and a thickness of about 3mm and a diameter of about 25mm and a thickness of about 2mm are particularly effective. These magnets have a magnetic field strength of between about 9,000 Gauss and about 13,000 Gauss and in a preferred embodiment have a magnetic field strength of between about 10,000 Gauss and about 11,300 Gauss.

The magnets may comprise a coating to protect the magnets from corrosive materials and to protect the magnets during cleaning of the article to which they are attached. A Ni-Cu-Ni coating with a thickness of about 15-20μm is sufficient, which protects the magnet against temperatures up to about 100°C. Hence, the probability that the magnets will lose their magnetism when exposed to high temperatures during washing or cleaning is minimized or at least reduced.

An embodiment of the article will now be described with reference to the pair of underpants 2 shown in FIGS 1-3.

The underpants 2 are formed from the preferred aforementioned two-way stretch material comprising about 54% polyester, about 30% cotton and about 16% elastane, such that the underpants conform to the contours of the body 4 of the wearer. Circular NdFeB magnets are coupled to the material of the underpants 2 to maintain them in position and ensure that they are not dislodged by rough treatment. FIG 1 shows three pairs of magnets 6 mounted to the underpants such that they lie adjacent a lower abdominal region of the body 4. FIG 2 shows three pairs of magnets 8 mounted to the underpants such that they lie adjacent a sacral region of the body 4 and one pair of magnets 10 mounted to the underpants such that they lie adjacent a lumbar region. FIG 3 shows the aforementioned magnets mounted in the lower abdominal, lumbar and sacral regions of the body and a pair of magnets 12 mounted to the underpants 2 such that they lie adjacent the perineum.

Mounting of the magnets to the underpants 2, could be achieved by any suitable means known in the art, such as stitching or using Velcro®. However, the Applicants have found that it is necessary to maintain the magnets, especially

adjacent magnets, rigidly in position to prevent the magnets deforming the article due to the attractive magnetic force between the magnets.

Therefore, a mounting member, such as a substantially rigid strip 14, is used to mount a pair of magnets to the underpants 2. The strip may be made of any suitable material known to persons skilled in the art, such as polyurethane, PVC or other rigid, light polymer. In one embodiment, as shown in FIG 7, the strip 14 comprises a number of slits 16 into which the ends of the magnets 6, 8, 10 or 12 are inserted. The rigid strip thus maintains the magnets in position and prevents adjacent magnets from sticking together. Alternatively, the strip 14 may be made from two separate strips bonded together sandwiching the magnets therebetween. In this example, a first strip may comprise moulded recesses to accommodate the magnets and a second strip may be bonded to the first to maintain the magnets in position. It will be appreciated by persons skilled in the art that there are numerous alternative slit arrangements and/or recess arrangements that could be used to hold the magnets.

Each strip may be removably inserted into one or more pockets formed in or attached to the material of the underpants or each strip may be stitched to the underpants. Where pockets are employed, the pockets are made from a non-stretch material to prevent the magnets from turning over/twisting.

The mounting members in the form of strips 14 are coupled to the underpants in a substantially horizontal manner as shown in FIGS 1 and 2. Attaching the mounting members substantially horizontally rather than substantially vertically more effectively prevents clumping of the magnets. Substantially horizontal orientation of the magnets on the sacrum and lumbar

areas for example causes the magnets to naturally "unclump" when the pants are pulled up by a patient.

In the embodiment shown in FIGS 1-3, the circular magnets 8,10 are 25mm in diameter and 2mm in thickness and are coupled to the underpants 2 via strips 12 such that the magnets lie adjacent the lumbar region and sacrum region in four pairs substantially horizontally, substantially perpendicular to the spine, with the north pole of the magnets 8, 10 facing the body 4. Six 25mm x 2mm magnets 6 are arranged in three pairs on the article substantially horizontally, substantially perpendicular to the spine adjacent the abdomen area with the north pole of the magnets 6 facing the body 4.

With reference to FIG 3,one or two magnets, either 25mm x 2mm or 10mm x 3mm magnets 12 are attached to the underpants such that they lie adjacent the perineum area. Magnets 12 are located between about 6mm and about 12mm apart and preferably about 6mm apart with a north pole of one magnet facing the skin and the south pole of the other magnet facing the skin. This creates the following stimulation/capillary effect. The south-facing magnet constricts blood flow and the north-facing magnet promotes blood flow. The north (negative) pole has the effect of increasing alkalinity and reducing acidity by reducing the hydrogen ion and increasing pH. The increased alkalinity brings the tissue back to normal and increases oxygen supply to the cell. The increased oxygen flow charges and properly increases cellular DNA. It slows down overactive organs, controls inflammatory conditions (redness warmth and swelling), arrests bacteria and growths and reduces congestion. The south (positive) pole stimulates bacteria and increases activity and acidity. It expands, softens and relaxes tissues by increasing inter and intracellular fluids. It also dilates blood vessels (is a

vasodilator). · One of the net effects is to increase oxygen within the blood thus helping to destroy anaerobic pathogens and increase nutrients. This acts to regenerate necrotic nerve endings leading to healthier muscle tissue and a clear pathway for electrical current to the CNS.

It will be appreciated that whilst the number and positions of the magnets shown in FIGS 1-3 achieves effective treatment of conditions such as incontinence, prostatic inflammation, faecal incontinence, bedwetting, period pain, menopausal problems, the treatment of other conditions may require an alternative number and alternative positioning of magnets over different and/or additional acupoint regions. However, the particular magnets selected by the Applicants enable the magnets to be located adjacent the body generally in the region of the acupoints relevant to the condition being treated. The magnetic field strength and penetration of the magnetic field produces a "flooding effect" whereby a plurality of acupoints in the adjacent body region are stimulated. This avoids the problems of accurately locating the acupoints and maintaining the magnets over these acupoints. The magnets are in the general region of the acupoints and may move naturally with the article as the wearer moves without any deterioration in the stimulation of the acupoints. The effective range of the 25mm diameter magnets is about 50mm beyond the edge of the magnet and the effective range of the 10mm diameter magnets is about 40mm beyond the edge of the magnet.

The underpants 2 may be in the form of conventional underpants and therefore may be worn at any time of day or night without inconvenience. The pants 2 may be worn, for example, at night-time for approximately 6 to 8 hours, when a person is asleep. However, they can be worn between 18-24 hours per day. Wearing the pants 2 for longer than 6 to 8 hours per day will result in

improvement in conditions such as incontinence in a shorter timeframe. The Applicants have found that an initial treatment period of 5-16 weeks results in a measurable reduction in incontinence being experienced. However, in some cases, measurable improvements have been identified after a treatment period of as little as a week or less. Although patients can stop wearing the article at this time, it is recommended that they continue to be worn at least twice a week for the same time periods for the next 12 months to reduce the chance of incontinence returning.

Since pelvic floor muscles are known to aid treatment of certain medical conditions in the pelvic region, such as urinary and faecal incontinence and enuresis, pelvic floor exercises are to be employed in accordance with the present invention. Once treatment with the aforementioned underpants 2 has been undertaken for the recommended period, the wearer uses feedback device 50 (shown in FIGS 4 and 5) to help correct identification of the pelvic floor muscles, thus addressing one of the problems inherent in performing pelvic floor exercises.

With reference to FIGS 4 and 5, feedback device 50 comprises inflation means in the form of deformable bulb 52 coupled to a pressure gauge in the form of an aneroid sphygmomanometer 54. Bulb 52 and aneroid sphygmomanometer 54 are coupled via tube 56 to a probe/sensor 58, which is for insertion into an orifice in the pelvic region. When the probe is inserted into the vagina or anus, bulb 52 is pumped to inflate probe 58, the level of inflation being indicated on the gauge. When the pelvic floor muscles are correctly identified and exercised, aneroid sphygmomanometer 54 will register a deflection in the needle position on the gauge. Release valve 60 is coupled between bulb 52 and aneroid sphygmomanometer 54 to enable inflation or deflation of probe 58.

Once the pelvic floor muscles can be identified, known pelvic floor muscle (Kegel) exercises can be performed to strengthen the pelvic floor muscles. The probe and gauge can be used to determine the strength and/or tone of the muscles, thus providing feedback that improves these muscles. The biofeedback system also provides resistance for pelvic floor exercises thus increasing the tone and strength of these muscles.

Wearing of underpants 2 comprising the magnets that stimulate the acupoints, coupled with feedback device 50 and the pelvic floor exercises combine to provide the treatment method of the present invention that substantially reduces or eliminates one or more of the following conditions: incontinence, overactive bladder (OAB), faecal incontinence, bedwetting, prostrate conditions, enuresis, menopause problems, period pain. The method of the present invention is summarised in the flow chart in FIG 6. Article 2 stimulates the CNS via specific acupuncture points and revitalizes receptors of the pelvic floor and bladder nerves/muscles and related sites. After a period of stimulation, usually a period of weeks, the pelvic floor muscles are able to respond better to the CNS and can be exercised properly.

Nerve impulses are transmitted through the body by neurons, which are distinguished according to their general function: receptor or sensory neurons, motor neurons and interneurons. Interneurons form the largest group in the nervous system and they form connections between themselves and sensory neurons before transmission of control to motor neurons. The connecting axon between dendrites and terminal buttons in a neuron are protected by the myelin sheath. The myelin sheath can become compromised by low-grade chronic infections, which interfere with the neural transmission from the brain to receptor

sites, such as muscles and nerve endings, and receptor sites to the brain, which can become one of the major underlying causes of incontinence.

Magnetic impulses from the magnets of the article of the present invention cause blood perfusion into the cells of the pelvic area, which helps restore the myelin sheath back to a normal and healthy state (without infections), which enables neural transmissions to function correctly in the incontinent person. Restoring the myelin sheath integrity enables the complex urinary system to perform correctly and reduce or eliminate incontinence.

Another embodiment of the article of the present invention in the form of an undergarment is shown in FIGS 8 and 9. The undergarment is in the form of a longer pair of underpants 2 than shown in the first embodiment shown in FIGS 1-3, such that the underpants 2 additionally cover more of the wearer's lower and central abdomen region and more of the lumbar region and lower back of the wearer. Optionally, leg portions 20 of the underpants 2 may cover upper regions of the wearer's legs. Alternatively, the underpants 2 of this embodiment may omit the leg portions 20 that cover upper regions of the wearer's legs.

With reference to FIG 8, the underpants 2 comprise three pairs of magnets 6 mounted to the underpants via the mounting member 14, such that they lie adjacent the lower abdominal region of the wearer's body 4. With reference to FIG 9, the underpants 2 also comprise three pairs of magnets 8 mounted to the underpants such that they lie adjacent a sacral region of the body 4 and one pair of magnets 10 mounted to the underpants such that they lie adjacent the lumbar region. The underpants 2 also comprise at least one magnet adjacent to the perineum region as described in the previous embodiments. As shown in FIGS 8 and 9, this embodiment of the article comprises a locator band 22 formed about an

upper region of the underpants 2, but below the waistband 3 to aid the wearer in positioning the pants such that the magnets 10 lie above the hipbone and below the rib cage adjacent the lumbar region to stimulate known acupoints in that region. The locator band 22 is elasticised and also contributes to maintaining the underpants securely in place and to supporting the mass of the magnets 6, 8, 10, 12 coupled to the underpants 2. The locator band 22 also aids wearers in positioning the pants when they try the underpants on for the first time.

Another embodiment of the present invention for the treatment of enuresis and nocturnal enuresis in younger people comprises fewer magnets than shown in FIGS 1-3 and FIGS 8 and 9. Fewer magnets are used to accommodate smaller body sizes and to reduce the magnetic flux penetrating the body. For example, instead of the 16 magnets shown in the adult versions of FIGS 1-3 and FIGS 8-9, a child's version may comprise 12 magnets with, for example, one pair of magnets 6 being omitted from the lower abdominal region and one pair of magnets 8 being omitted from the sacral region. However, children aged approximately 9-14 years may be able to wear underpants 2 according to the present invention comprising having the same configuration of magnets.

Recommended periods of wear are also reduced for younger people. For example, children aged approximately 5 to 9 years may only wear the underpants 2 for one to two hours before bed for the first three days and then wear the pants throughout the night. This allows the children's body to adjust to magnetic treatment.

The magnets of underpants 2 simultaneously stimulate the BL23 acupoint in the lumbar region and the BL25 acupoint on the abdomen for the treatment of,

for example, incontinence. However, stimulation of the acupoint BL40 on the back of the knee is also known to treat incontinence and the Applicant has found that simultaneous stimulation of these three sites produces effective treatment of various conditions in and around the pelvic region to stimulate, strengthen and tone the pelvic floor muscles. Therefore, the article comprising magnets may be in the form of a knee strap comprising magnets, the knee strap formed from the same material as the underpants described above. One or more magnets, about 25mm or about 10mm in diameter may be employed in these articles. Alternatively, magnets about 3mm in diameter having a magnetic flux density of about 2,500 Gauss may be employed.

Other acupoints in the ankle and lower leg are also known to be related to the treatment of at least incontinence. The acupoints are located below the ankle and above the ankle on the inside of the foot/ankle. Therefore, article 2 may be in the form of a toeless and possibly heelless sock that covers one or more of the aforementioned acupoints about the ankle and lower leg. One or more magnets, such as those used in article 2, is incorporated by any suitable means into the toeless/heelless sock and the magnets located such that when the sock is worn, the one or more magnets lie adjacent the acupoints in the ankle and lower leg. Mounting members as previously described herein may be employed to couple the magnets to the sock and to prevent the magnets from clumping together.

The toeless/heelless sock may be worn in addition to or as an alternative to article 2. In particular, the sock may be worn with shoes during the day to maintain treatment if, for example, the patient does not wish to wear the article 2, whether in the form of the underpants or the knee strap, during the day. It has

been found that wearing the sock speeds up treatment of, for example, incontinence in the wearer.

Other applications of the invention include, but are not limited to, revitalizing and toning the pelvic floor muscles; toning and strengthening of the vaginal wall to enhance physical intimacy; reducing period pain and menopausal symptoms; treating fecal incontinence, enuresis, overactive bladder, prolapsed uterus, impotence, nocturia, lower abdominal pain, menorrhalgia and prostrate problems.

Throughout the specification the aim has been to describe the invention without limiting the invention to any one embodiment or specific collection of features. Persons skilled in the relevant art may realize variations from the specific embodiments that will nonetheless fall within the scope of the invention. For example, it is envisaged that more than two magnets may be mounted to a single mounting member if required.

Dated this Twenty-Ninth day of August 2003

NEPHI PTY LTD

By their Patent Attorneys

FISHER ADAMS KELLY

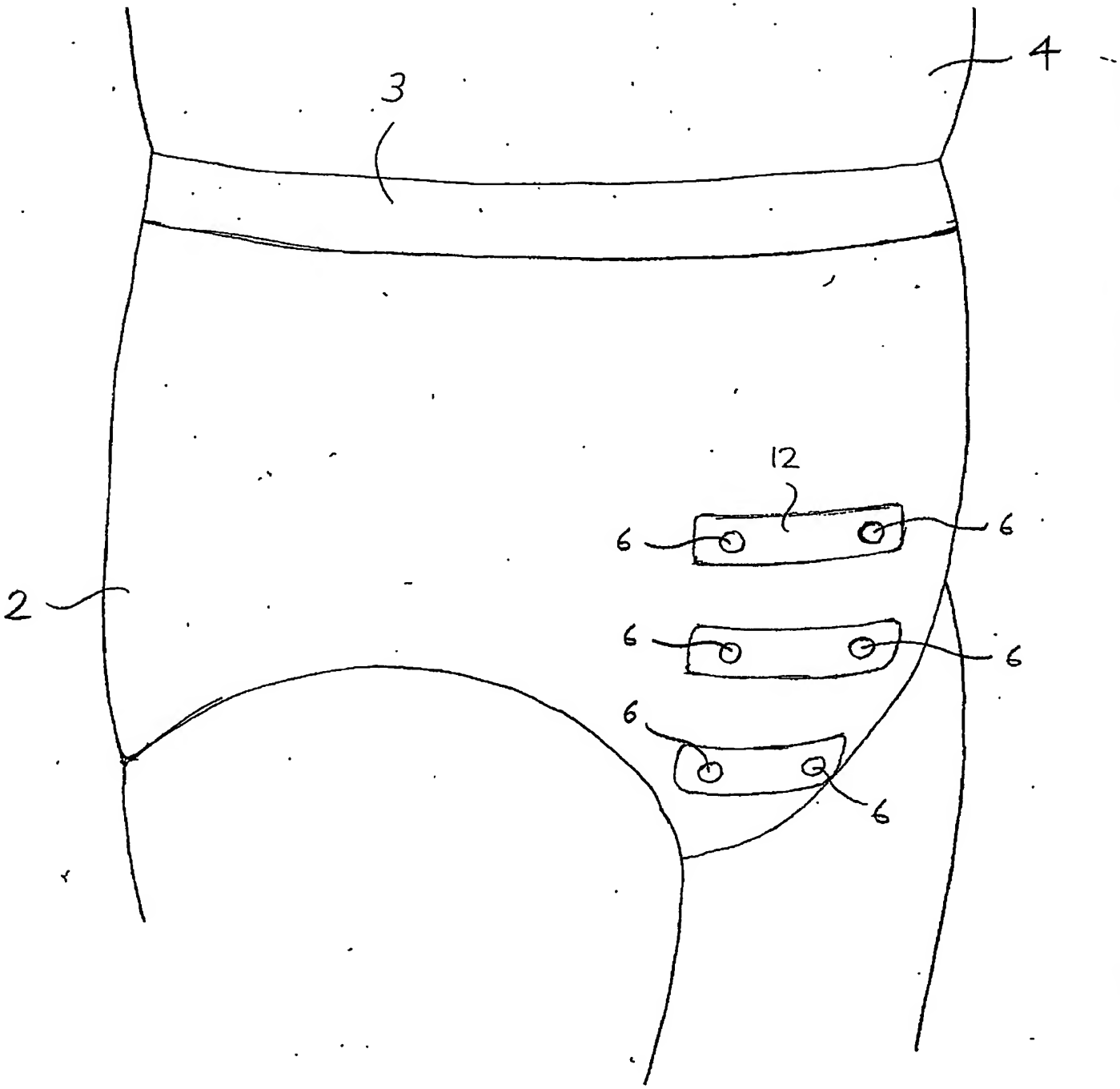


FIG 1

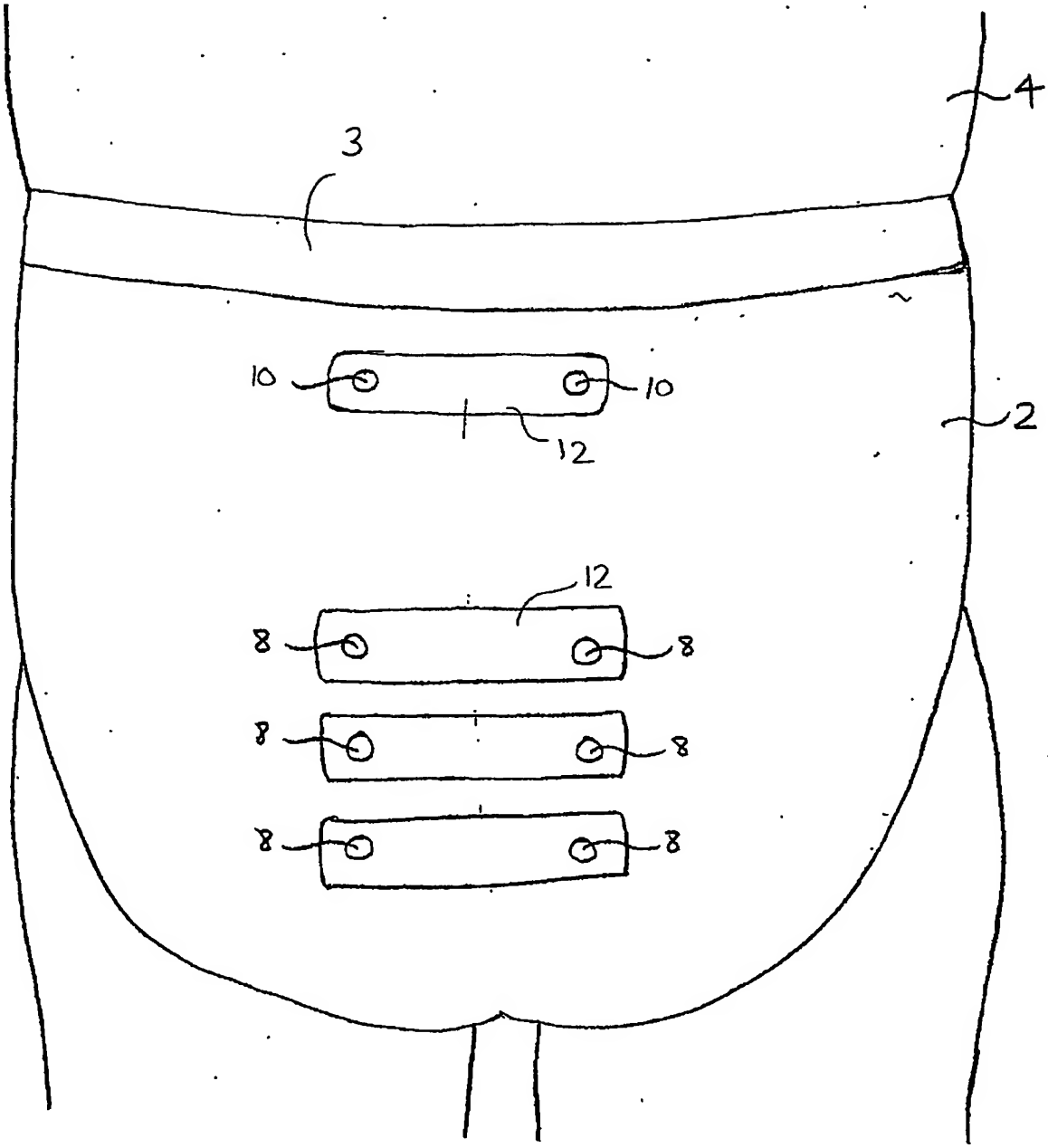


FIG 2

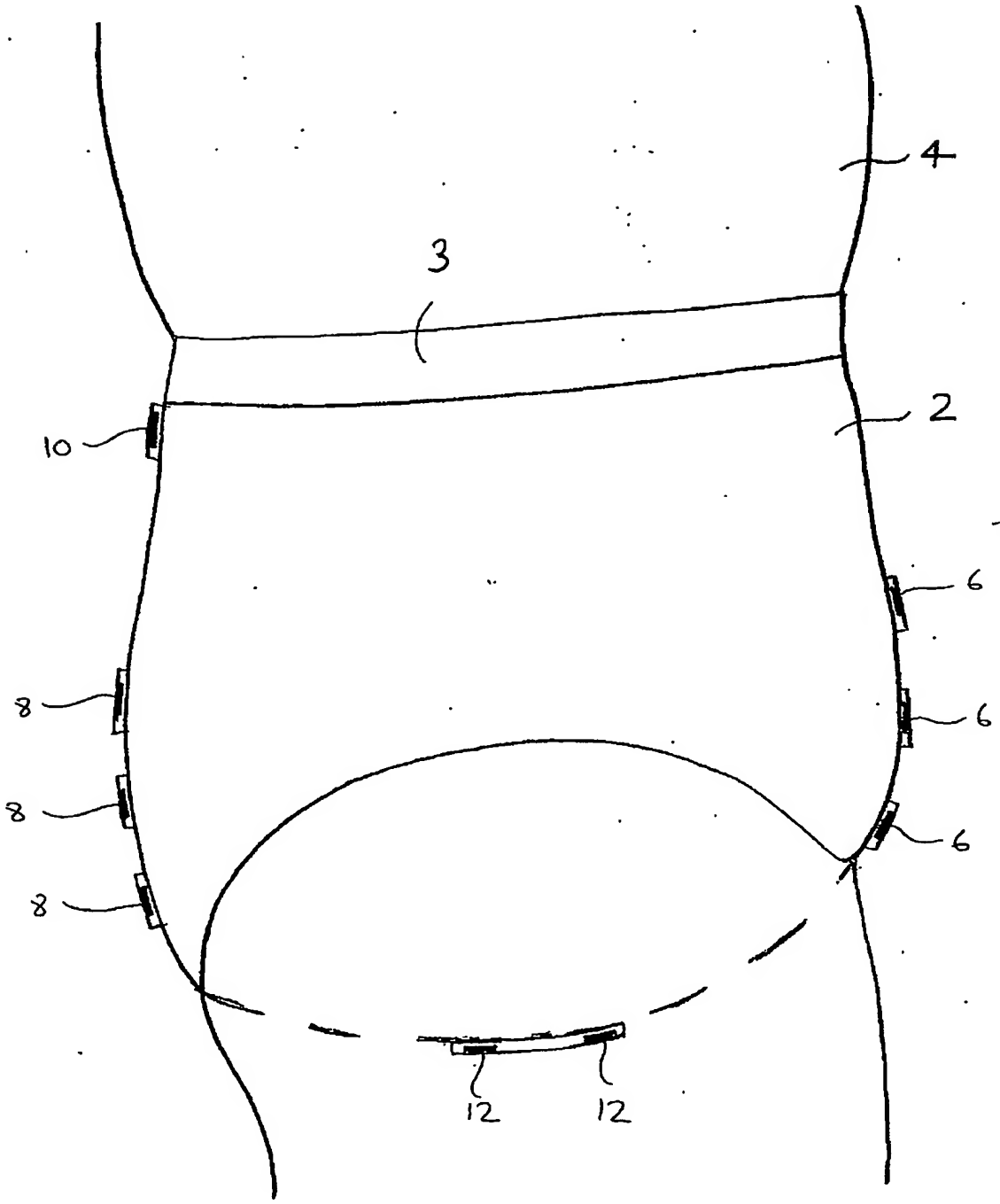


FIG 3

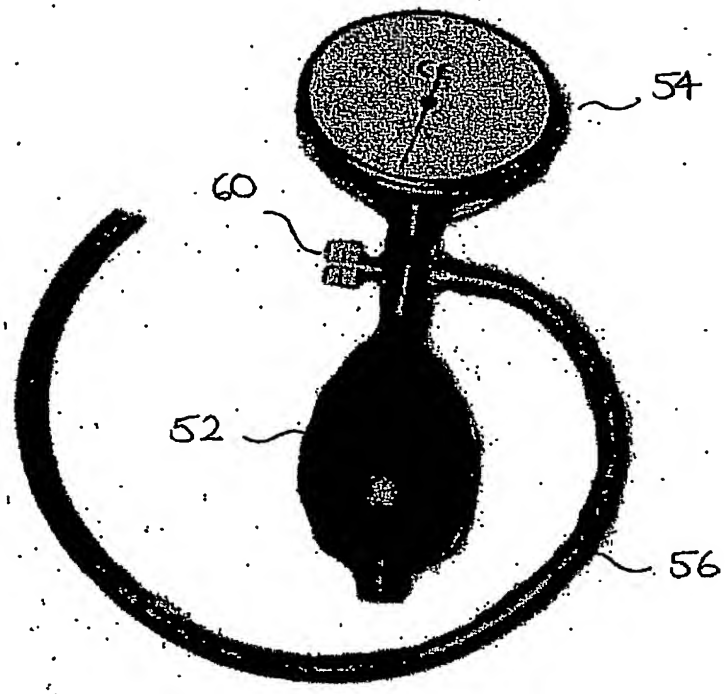


FIG 4

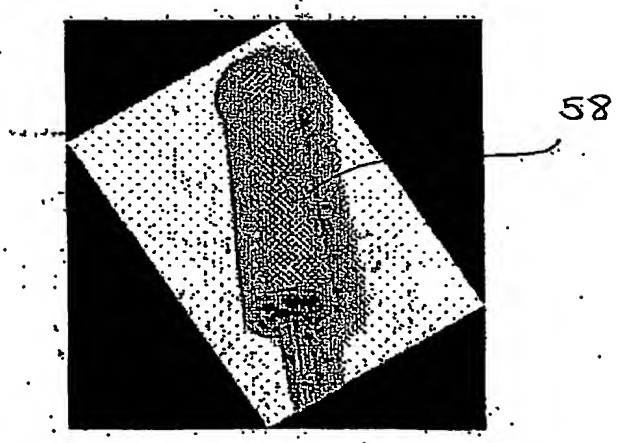


FIG 5

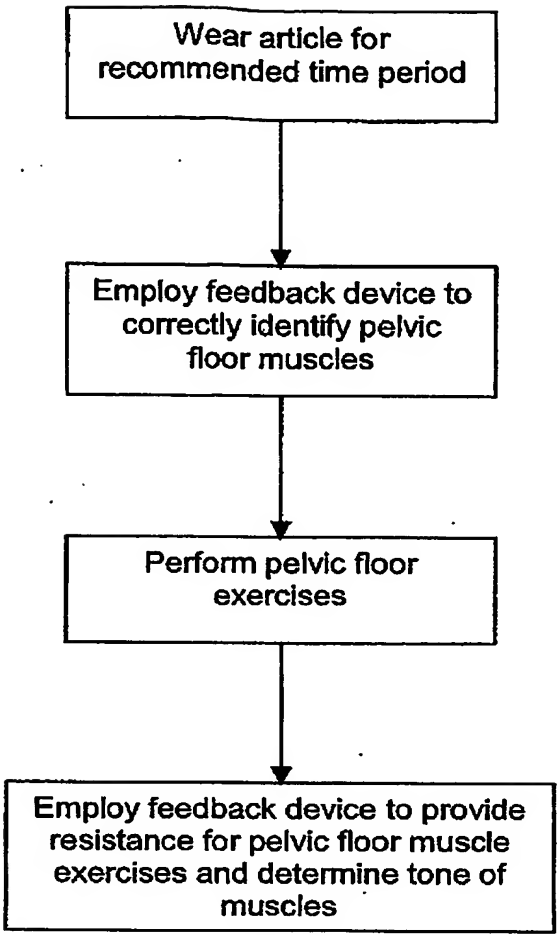
Wear article for recommended time period
Employ feedback device to correctly identify pelvic floor muscles
Perform pelvic floor exercises
Employ feedback device to provide resistance for pelvic floor muscle exercises and determine tone of muscles

FIG 6

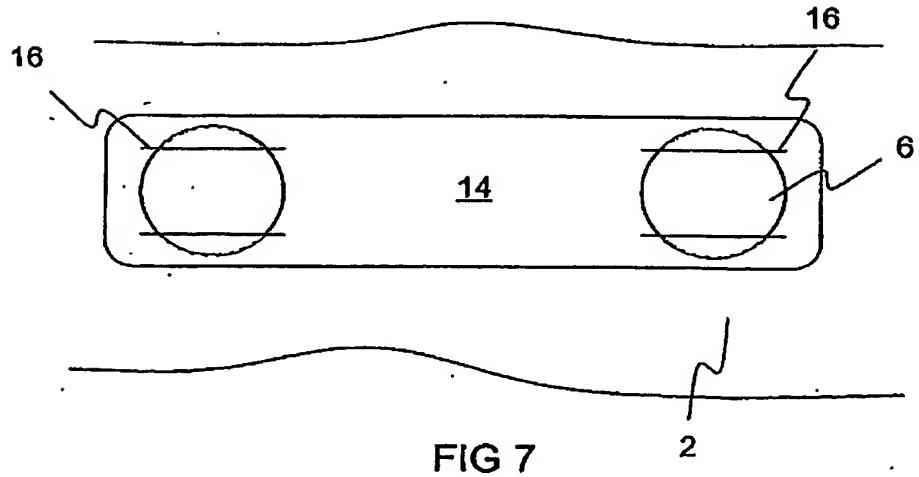
16
16
6
14
2

FIG 7

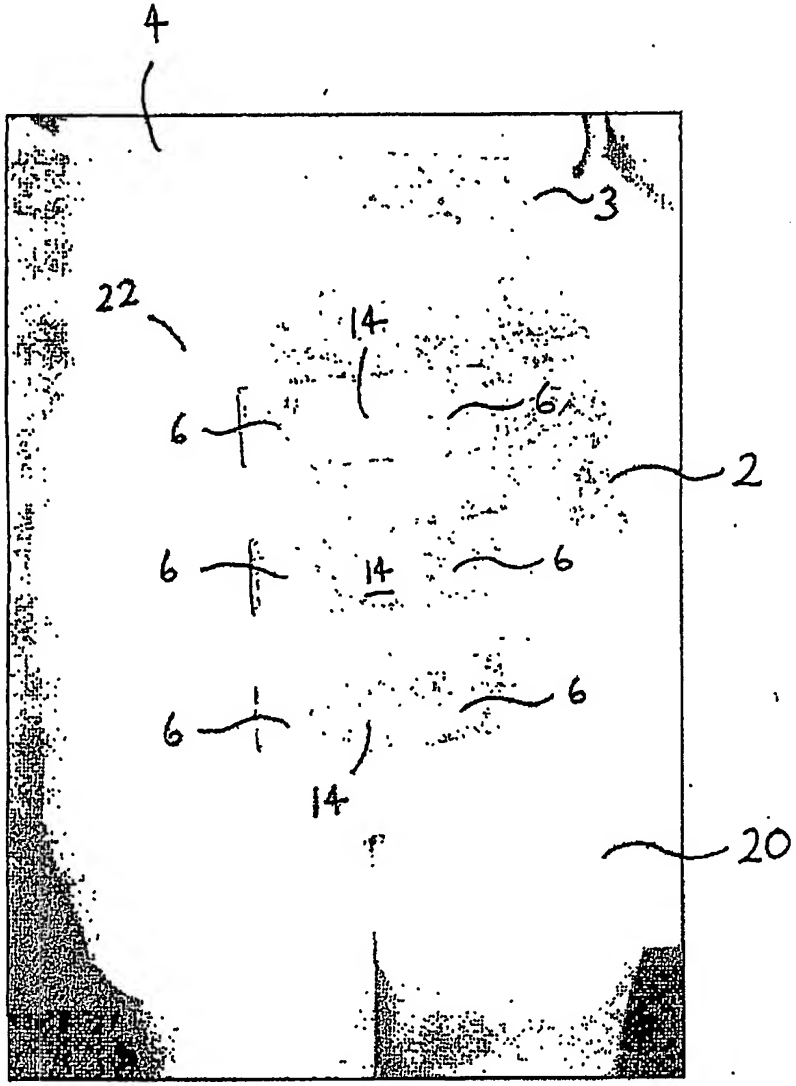


FIG. 8

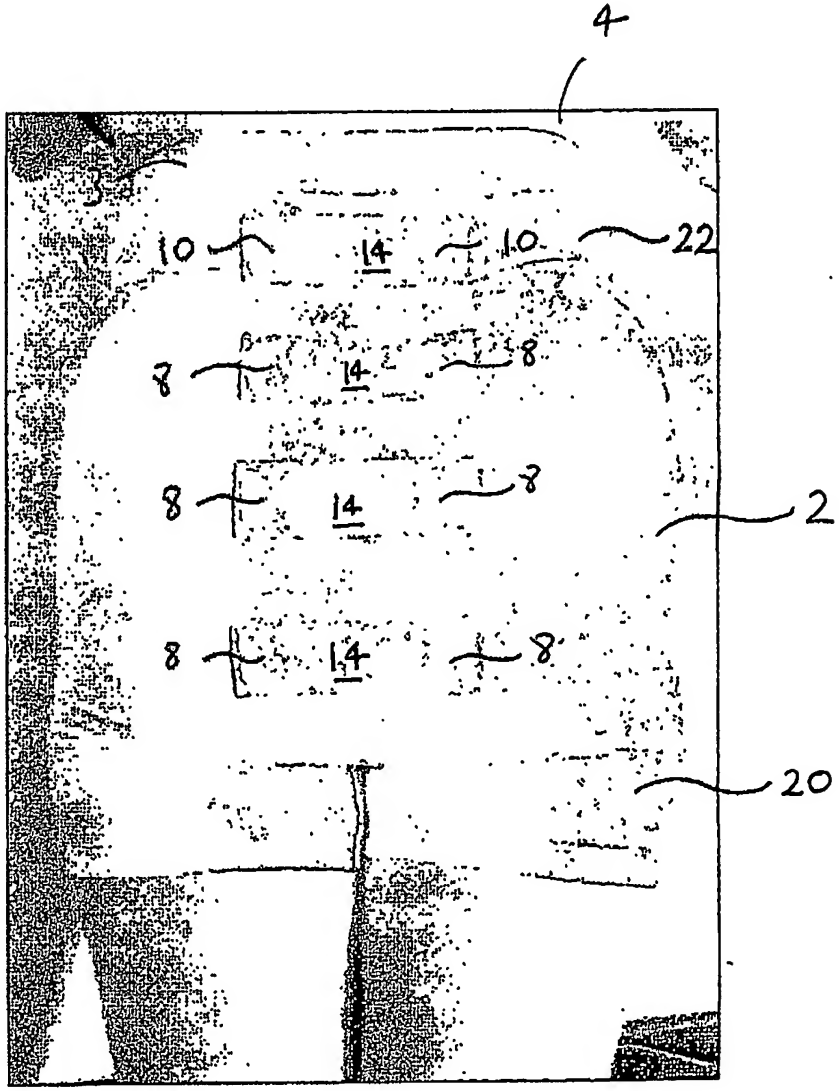


FIG. 9

**This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record**

## BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☑ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☑ FADED TEXT OR DRAWING
- ☑ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

**IMAGES ARE BEST AVAILABLE COPY.**
**As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.**